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10/538,150

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Sharon Katrina Watson

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EXAMINER

LEE, JOHN W

ART UNIT

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2624

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/538,150 | Applicant(s) WATSON ET AL. | |
| | Examiner JOHN Wahnkyo LEE | Art Unit 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19,21,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,20,22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the Pre-Appeal Brief filed on 16 July 2009, PROSECUTION IS HEREBY REOPENED. New ground rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Samir A. Ahmed/

Supervisory Patent Examiner, Art Unit 262410538150

Claim Objections

2. Claim 25 is objected to because of the following informalities: The claim is not clear whether it is an independent or a dependent claim. The examiner requires the applicant to rewrite claim 25 that can be consistent with the other claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-18, 20 and 22 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent¹ and recent Federal Circuit decisions² indicate that a statutory “process” under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the “machine or transformation test”, whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590”). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor positively tie to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

¹ *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

² *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18, 20, 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The “defining respective regions of specified extent within the image around respective said locations” recited in claims 1 and 22 of the claim limitations (a) and (b) and claim limitation (e) of claim 22 are not disclosed by the originally filed specification. Claims 2-18, 20 and 25 are also rejected under 112, first paragraph for the same reason.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-18, 20, 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reasons are as follows: The “which” in claim limitation (a) in claims 1 and 22 is not clear whether it is trying to indicate “locations” or “objects.”; “respective said regions” in claim limitations (c) and (d) in claims 1 and 22; “at least one respective said contour” in claim limitations (d) in claims 1 and 22; “at least said measure of concavity of a contour” in claim limitation (e) in claim 22. Claims 2-18, 20 and 25 are also rejected under 112, second paragraph for the same reason.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-13, 14, 17-18, 20, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms") in view of Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells").

Regarding claim 1, Netsch teaches a method for the automated analysis of a digital image comprising an array of pixels (Chapter III. section A.; page 776, "image pixels") including the successive steps of: (a) identifying the locations of objects (Chapter III. section A.; page 776, "circular spots") within the image which have specified intensity (Chapter III. section A.; page 776, "local contrast C") and size (Chapter III. section A.; page 776, "size D") characteristics; (b) defining respective regions of specified extent within the image around respective said locations (Chapter III. section A.; page 776, "mark a spot"); (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function" and "Gaussian function is a type of a probability density function"). However, the last claim limitation is not disclosed by

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Netsch. However, Madachy discloses (d) estimating the curvature of at least one respective said contour within respective said regions and producing a measure of any concavity thereof (SHAPE, pages 373, “R(i)” and “curvature”).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Madachy’s method in Metch’s method to provide automated detection of microcalcifications as suggested by Netch (abstract).

Regarding claim 2, Madachy teaches all the previous claim limitation except the one specified in claim 2. However, Netsch teaches wherein step (a) comprising the application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, “circularly-symmetric Gaussian function”).

Regarding claim 3, Netch further teaches the image is filtered at a plurality of resolutions of increasing scale (Figure 4; section III. A Motivation and Outline; pages 776-777, “scales $h=1, \dots$ ”).

Regarding claim 4, Netch further teaches locations are identified in accordance with the locations of respective local extrema (abstract, “local maxima”) in the output of said filter (abstract, “possible locations of ... local maxima ... filtered image ...”).

Regarding claim 5, Netch further teaches including the step of sorting, in order of intensity (section III A. Motivations and Outline, “range of scales”), local extrema (section III A. Motivations and Outline, “local maxima”) in the output of said filter (abstract, “possible locations of ... local maxima ... filtered image ...”) and selecting for further analysis only those objects which correspond to a specified proportion of said

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extrema in such order (section III A. Motivations and Outline, "Detection ... filter ... threshold").

Regarding claim 6, Madachy further discloses following step (a): selecting an intensity threshold (TEXTURE, pages 373, "15%") related to the mean intensity of pixels (TEXTURE, pages 373, "mean value") within the image in neighbourhoods of said locations (TEXTURE, page 373); creating a binary image according to whether pixels in the first-mentioned image (Figure 2; TEXTURE, pages 373) are above or below said threshold (TEXTURE, pages 373, "15%"); identifying regions in the binary image composed of connected pixels which are below said threshold in the first-mentioned image (Figure 2; TEXTURE, page 373, "white pixels"); and rejecting from further analysis those objects which correspond to such regions in the binary image which fall below a specified size or thickness (TEXTURE, page 373, "larger than .. ").

Regarding claim 7, Madachy further teaches wherein step (c) comprises, for respective said regions (TEXTURE, page 373, "subregions") deriving respective first (Figure 2; TEXTURE, page 373, "white pixel region") and second said contours (TEXTURE, page 373, "black pixel region") having respectively lower (TEXTURE, page 373, "optical density being 15% lower than mean value") and higher resolutions (TEXTURE, page 373, "optical density being 15% greater than mean value"), determining whether the sizes and locations of said first and second contours are consistent within specified criteria and, if so consistent, selecting said second contour for step (d) (TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation.").

Regarding claim 8, Madachy further teaches the first said contour is derived by: seeking within the region one or more contours of respective specified intensities (Figure 2; TEXTURE, page 373, “white pixel region” and “black pixel region”); determining whether the or each such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, “continuous contours ... fixed size”; TEXTURE, page 373, “the black and white regions are ... regions larger than 2 ... operation.”); and if more than one such contour is a closed contour and meets such criteria, selecting from the same the contour of the lowest intensity (Figure 2; TEXTURE, page 373, “white pixel region”).

Regarding claim 9, Madachy further teaches wherein said specified intensities (Figure 2; TEXTURE, page 373, “white pixel region”) are no greater than that which corresponds to the contour of highest edge strength within the respective region (TEXTURE, page 373, “black pixel region”).

Regarding claim 10, Netch further teaches wherein step (a) comprising the application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, “circularly-symmetric Gaussian function”) and said first contour is derived by seeking one or more contours in the output of said filter for the respective region and said specified intensities are no greater than the zero level in such output (Figs. 3-5; equations (1)-(6); section III. A. Motivation and Outline, page 776, “circularly-symmetric Gaussian function”).

Regarding claim 11, Madachy further discloses the second said contour is derived by: seeking within the region a plurality of contours of respective specified

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intensities ranging between the lowest and highest intensities within the region (Figure 2; TEXTURE, page 373, “white pixel region” and “black pixel region”); determining whether each such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, “continuous contours ... fixed size”; TEXTURE, page 373, “the black and white regions are ... regions larger than 2 ... operation.”); and if more than one such contour is a closed contour and meets such criteria, selecting from the same the contour having the highest edge strength (Figure 2; TEXTURE, page 373, “white pixel region”).

Regarding claim 12, Netch further teaches step (d) including the application of a Probability Density Association Filter to respective said contours (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, “circularly-symmetric Gaussian function” and “Gaussian function is a type of a probability density function”).

Regarding claim 13, Netch further teaches step (d) comprising, for respective said contours (III D. Feature Estimation by Signatures; pages 778, “cylinder”): measuring the curvature of the contour at a plurality of points around the contour, convexity and concavity being of opposite sign (equation (7); III D. Feature Estimation by Signatures; pages 778, “cylinder”); setting convex values of such curvature to zero (equation (7); III D. Feature Estimation by Signatures; pages 778, “cylinder”); plotting resultant values of curvature at said points against a measure of the distance of the respective point along the contour (Figs. 7-10); and computing as said measure of concavity the line integral of such plot (equations (7)-(16)).

Regarding claim 14, Madachy further discloses further comprising the step of: (e) classifying objects into one of at least two classes (CELL CLASSIFICATION, page 373, “parameters”) in accordance with a function of said measure of concavity of a contour (SHAPE, page 373, “R(i)”) corresponding to the respective object and a measure of the mean intensity (TEXTURE, page 373, “mean value”) of the respective object.

Regarding claim 17, Madachy further discloses further comprising the step of: (f) counting the number of objects classified into a specified one of said classes (PREVIOUS EFFORTS, page 372, “counted mitoses in breast cancer ...”).

Regarding claim 18, Madachy further discloses wherein the image is of a histological or cytology specimen or of a soil sample (INTRODUCTION, page 372, “pre-scored specimens”).

Regarding claim 20, Madachy further discloses the image being of a section of breast tissue and said specified class is identified as the class of mitotic epithelial cell nuclei (PREVIOUS EFFORT, page 372, “counted mitoses in breast cancer ...”).

Regarding claim 22, Netsch discloses a method for the automated identification of mitotic activity from a digital image of a histological specimen, including the steps of: (a) identifying the locations of objects (Chapter III. section A.; page 776, “circular spots”) within the image which have specified intensity (Chapter III. section A.; page 776, “local contrast C”) and size (Chapter III. section A.; page 776, “size D”) characteristics associated with epithelial cell nuclei (Fig. 6; Chapter I, “Breast cancer”); (b) defining regions of specified extent within the image which contain respective said objects (Chapter III. section A.; page 776, “mark a spot”); (c) deriving from the data within

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respective said regions one or more respective closed contours comprising points of equal intensities (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, “circularly-symmetric Gaussian function” and “Gaussian function is a type of a probability density function”); The last two claim limitation is not disclosed by Netsch. However, Madachy discloses (d) estimating the curvature of at least one respective said contour within respective said regions at least to produce a measure of any concavity thereof (SHAPE, pages 373, “R(i)” and “curvature”). (e) classifying objects as representing mitotic cell nuclei as a function of at least said measure of concavity of a contour corresponding to the respective object (TABLES 1 and 2; page 374, “parameter statistics” and “classification”).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Madachy’s method in Metch’s method to provide automated detection of microcalcifications as suggested by Netsch (abstract).

Regarding claim 25, Madachy further discloses a computer program comprising instructions to cause a computer to execute a method according to claim 1 (METHOD, page 373, “Gould/Denaza IP8500 image processor on a VAX host”).

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. (“Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms”) in view of Soni et al. (US 5,363,850).

Regarding claim 15, Netsch teaches all the previous claim limitation except the one specified in claim 15. However, Soni discloses using a Fisher classifier (claims 5 and 6, "Fisher classification").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Soni's invention in Netsch's method to provide high resolution as suggested by Soni (col. 1, lines 8-10).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms") in view of DeLong (US 2002/0012466).

Regarding claim 16, Netsch teaches all the previous claim limitation except the one specified in claim 16. However, DeLong discloses the intensities of respective objects are normalised prior to step (e) (Fig. 2; claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use DeLong's invention in Netsch's method to provide an image analysis process which can cyclically and interactively approximate the wished and ideas of a user without the user having to have detailed knowledge of the image processing itself (paragraph [0006]).

JOHN Wahnkyo LEE

/Samir A. Ahmed/

Supervisory Patent Examiner, Art Unit 2624